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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/515,369	02/29/2000	Paul B. Fisher	0575/56778/JPW/JML	1885

7590 09/22/2003

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT PAPER NUMBER

1636

DATE MAILED: 09/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b>	<b>Application No.</b> 09/515,369	<b>Applicant(s)</b> FISHER ET AL.	
	<b>Examiner</b> Daniel M Sullivan	<b>Art Unit</b> 1636	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 04 August 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. **ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).**

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: 2,5 and 15.

Claim(s) rejected: 1,3,4,6-9,14 and 16-20.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☒ The proposed drawing correction filed on 04 August 2003 is a) ☒ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Continuation of 2. NOTE: Applicant has amended claims 1 and 14 such that the claims are now encompass a promoter molecule that hybridizes to the nucleic acid sequence set forth in SEQ ID NO: 1 from the thymidine at position 1 to a cytosine at position 2240. The new limitation replaces the limitation that the promoter molecule is at least about 80% identical to SEQ ID NO: 1 over the same region. In substituting hybridizing language for percent identity, Applicant has expanded the scope of the claims such that new issues would have to be addressed in the examination thereof. First, the claims at issue in the Final Office Action were limited to having a certain degree of similarity to the disclosed SEQ ID NO: 1 over a defined region of the molecule. In contrast, because hybridization under stringent conditions can occur between molecules having a high degree of localized similarity and little or no similarity over the full length of the molecule, the nucleic acids encompassed by the claims in the proposed amendment need not be 80% identical to the region of SEQ ID NO: 1 from the thymidine at position 1 to the cytosine at position 2240. Furthermore, the specification cites Sambrook et al. as an example of hybridization conditions that meet the limitation of "stringent". However, Sambrook et al. provides various hybridization conditions ranging from low to high stringency. As there is nothing in the specification or claims that limit the degree of stringency of the hybridization conditions, the claims encompass nucleic acids that hybridize under conditions that would allow for hybridization of sequences that are less than 80% identical to the specified region of SEQ ID NO: 1..

Continuation of 5. does NOT place the application in condition for allowance because: In the "REMARKS", Applicant traverses the outstanding written description rejection on the grounds that the recitation of 80% sequence identity is a "relevant identifying characteristic". Applicant cites the Written Description Guidelines and points out that relevant identifying characteristics include structural characteristics. This argument has been fully considered but is not found persuasive because, as pointed out in the previous Office Action, the specification provides no correlation of the recited structure with the disclosed function. Applicant is reminded that the claims are directed to a nucleic acid having at least about 80% structural similarity to a disclosed polynucleotide and defined functional characteristics. The structural limitation is not a relevant identifying characteristic of the claimed invention because many, if not most nucleic acids that meet the limitation are not encompassed by the claims. Had the specification disclosed the portions of the nucleic acid molecule that are required for the recited function and those that could be modified without affecting function, the skilled artisan would be able to envision the full scope of the claimed invention (i.e., nucleic acid molecules having 80% structural similarity and the recited function). However, no such description of functionally relevant portions of the nucleic acid is provided. Applicant further argues that the nucleic acids encompassed by the structural limitations and having the functional characteristics of the claimed promoter would be readily apparent based on teachings as to how one of ordinary skill could experiment to determine which of the nucleic acids that meet the structural limitation also have the recited function (paragraph bridging pages 9-10). This argument has been fully considered but is not found persuasive because an adequate written description of a DNA requires more than a reference to a potential method for isolating it; what is required is a description of the DNA itself. Applicant is reminded that, even if the specification would enable the skilled artisan to identify what is claimed by experimental means, the written description provision of 35 U.S.C. §112 is severable from its enablement provision (*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, at 1115).

It is noted that, were the nucleic acids limited to a structure that defines a genus wherein species having the recited function would be expected to predominate, the claimed subject matter would be adequately described. Limiting the claims to a nucleic acid having at least 95% identity to the nucleic acid sequence set forth in SEQ ID NO: 1 from the thymidine at position 1 to a cytosine at position 2240 would therefore overcome the written description rejection. Support for such a limitation can be found in the specification at page 15, line 24..



**JAMES KETTER**  
**PRIMARY EXAMINER**